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| 09/849,809 | 05/04/2001 | Mark W. Perlin | PERLIN-10 | 8918 |
| 7590 | 11/22/2006 | | EXAMINER | |
| | | | SMITH, CAROLYN L | |
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| | | | 1631 | |
| DATE MAILED: 11/22/2006 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

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|------------------------------|------------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/849,809 | PERLIN, MARK W. | |
| | Examiner Carolyn L. Smith | Art Unit 1631 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 06 September 2006.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-4,8,9,11 and 12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-4,8,9,11 and 12 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Applicant's amendments and remarks, filed 9/6/06, are acknowledged. Amended claims 1, 8, 9, and 11 and cancelled claims 5-7, 10, and 13-16 are acknowledged.

Applicant's arguments, filed 9/6/06, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from the previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 1-4, 8-9, and 11-12 are herein under examination.

Claims Rejected Under 35 U.S.C. § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4 and 8-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. These rejections are necessitated by amendment.

Claim 1 recites detecting step (c) to produce a single measurement and then combining step (d) which combines a plurality of measurements which lack clarity. The relationship between the steps is unclear as step (c) involves a single measurement and step (d) involves a

plurality of measurements that do not necessarily include the single measurement in step (c).

Clarification of the relationship between these two steps is requested. Claims 2-4 and 8-9 are also rejected due to their dependency from claim 1.

Claim 8 recites the limitation “is used to identify individuals” which is vague and indefinite. It is unclear if this limitation is intended to be a step or merely an intended result. If it is intended to be a “step”, it is unclear what active step(s) is/are intended to be encompassed by the “is used to” phrase. Clarification of this issue via clearer claim wording is requested.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Cheeseman (US 5,302,509) with support from Merriam-Webster online dictionary (“decouple” definition). This rejection is necessitated by amendment.

Cheeseman discloses a method of sequencing polynucleotides (title and abstract).

Cheeseman discloses amplifying a nucleic acid sample by polymerase chain reaction techniques to create many DNA molecules (col. 3, fourth and fifth paragraphs) which represents the amplifying step (a) of instant claims 1 and 11. Cheeseman discloses using a primer bound to the

DNA and extending the growing oligonucleotide chain with four fluorescently labeled 3'-blocked nucleotide triphosphates (NTPs) (col. 3, line 65 to col. 4, line 22 and col. 4, lines 63-68) which represents the extending a sequencing primer bound to the DNA product in the presence of terminating nucleotide analogs to produce a collection of labeled nucleic acid products, as stated in step 1(b) of instant claims 1 and 11. Cheeseman discloses each of the NTPs types (A, G, C, and T NTPs) will be labeled differently so as to be distinguishable by fluorescent spectroscopy or other optical means (col. 4, lines 5-10), identifying the labeled NTP in the DNA strand and repeating these steps until labeled NTPs can no longer be added (col. 2, lines 52-56 and 64-68) wherein the whole sequencing cell (chamber) with optical detection on a planar integrated optical system can be produced by photolithographic means and the planar optics allows many sequencing cells to be produced on the same substrate and illuminated by the same light source (col. 6, lines 58-66) which represents the detecting a total label present in the collection to produce a measurement that is determined without performing a DNA size separation on the products, as stated in step (c) of instant claims 1 and 11. According to the Merriam-Webster online dictionary, "decouple" means to separate. This definition is only being used to support the definition of "decouple" and is not being used as prior art. Cheeseman discloses a step (f) that is between the extending step (Cheeseman's step (e)) and detection step (Cheeseman's step (g)) (col. 2, lines 37-56) which represents a separation or decoupling of the detecting and extending steps, as stated in step c) of instant claims 1 and 11. Cheeseman discloses repeating the exposure of the four labeled NTPs to the sequence to add another base at each cycle to the growing oligonucleotide thereby identifying the next base until identification is complete (col. 7, third paragraph) with a DNA length example (col. 7, line 54) which represents

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combining a plurality of measurements to determine the DNA sequence information about the sample (as stated in step (d) of instant claims 1 and 11) as well as DNA sequence information corresponding to the length and plurality of bases in the DNA sequence (as stated in instant claims 3 and 4). Cheeseman discloses only one of the four NTP types being added at a time and read by its fluorescence (col. 5, lines 28-31), adjusting concentrations of bound NTPs with DNA such that there is a sufficient number of fluorescent molecules for optical detection (col. 5, lines 41-48) as well as dye concentrations in small areas to improve detection of fluorescence by improving signal-to-noise ratio (col. 6, lines 40-46) which represents each label measurement corresponds to an amount of terminating nucleotide, as stated in instant claim 2. Cheeseman discloses a solid-supported DNA, planar integrated optical system, optical fiber attached to DNA, fluorescent output detection by PIN photodiodes, and flow system (col. 6, lines 30-68; col. 7, fourth and fifth paragraphs) which represent the system for nucleic acid sequencing, as stated in instant claim 11.

Thus, Cheeseman anticipates instant claims 1-4 and 11.

Applicant summarizes a portion of the instant specification regarding decoupling. It is noted that the specification does not provide a clear and concise definition of the term “decoupled” as recited in instant claim 1. Therefore, this term has been given its broadest and reasonable interpretation (see included dictionary definition) to mean separated. It is noted that the detecting step is decoupled (separated) from the extending step in Cheeseman’s invention via a separating step (f), as seen in column 2 (lines 50-51). Applicant argues that Cheeseman’s method requires that DNA extension and label detection be coupled in every step. This

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statement is found unpersuasive as the extension and label detection steps are individual steps in Cheeseman's invention and these steps are further separated with a separation step (f). It is reiterated that the term "decoupled" has been interpreted broadly and reasonably due to the lack of a clear and concise definition in the specification.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 8, 9, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cheeseman (US 5,302,509) with support from Merriam-Webster online dictionary ("decouple" definition) as applied to claims 1-4 and 11 above; taken in view of Schumm et al. (US 20020012924). This rejection is necessitated by amendment.

Cheeseman discloses the limitations of instant claims 1-4 and 11 as stated in the 102 rejection above. Cheeseman does not describe using DNA sequence information is used to identify individuals (instant claim 8), DNA information is compared with a DNA database of genetic polymorphisms (instant claim 9), a PCR thermocycler (instant claim 12), or a computing device with a memory (instant claim 12).

Schumm et al. describe DNA sequencing with PCR including using a thermocycler (paragraphs 0089-0090), as stated in instant claim 12. Schumm et al. describe using DNA information to identify individuals (paragraph 0003), as stated in instant claim 8. Schumm et al. describe comparing DNA information with databases including genetic polymorphism data (paragraphs 0096, 0005, and abstract), as stated in instant claim 9. Schumm et al. describe using an ABI 377 Sequencer including putting data into a database using computer software (paragraph 0096) and scanning and analyzing for polymorphisms using Hitachi FMBIO fluorescent scanner with accompanying software (paragraph 0100) which represents a computing device with memory, as stated in instant claim 12.

Schumm et al. state DNA typing is commonly employed to identify the source of blood, saliva, semen, and other tissue found at a crime scene (paragraph 0004). Cheeseman state that his DNA sequencing method requires only small quantities of DNA for high sensitivity detection (col. 1, last paragraph). It would have been obvious to the person of ordinary skill in the art at the time the invention was made to analyze the small quantities for DNA sequencing, as stated by Cheeseman, with the databases and computing devices for criminal justice applications, as stated by Schumm et al., because this offers significant improvement over existing technology, bringing increased power and precision to DNA profiling for linkage analysis, criminal justice, paternity testing, and other forensic and medical uses, as stated by Schumm et al. (paragraph 0013). The person of ordinary skill in the art at the time the invention was made would have been motivated to make this modification in order to eliminate ambiguity in short DNA sequences, as stated by Cheeseman (col. 2, first paragraph) in forensic analysis which often require determination of whether more than one source of DNA sample is present, as stated by

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Schumm et al. (paragraph 0010). One of ordinary skill in the art would have expected success as both Cheeseman and Schumm et al. sequence DNA using PCR methods and Schumm et al. states their ability to identify and analyze particular polymorphic loci of DNA of various types, including single-stranded and double-stranded DNA from a variety of different sources (paragraph 0013).

Thus, Cheeseman in view of Schumm et al. make obvious the instant invention.

Applicant again argues that Cheeseman uses a coupled DNA extension and detection step. It is noted that the term “decoupled” has been given its broadest and reasonable interpretation (see included dictionary definition) to mean separated. It is noted that the detecting step is decoupled (separated) from the extending step in Cheeseman’s invention via a separating step (f), as seen in column 2 (lines 50-51). Applicant argues that the combination of Cheeseman and Schumm et al. necessarily includes a DNA sequencing step where Cheeseman use a coupled DNA extension and detection step and Schumm et al. use a DNA size separation step. This statement is found unpersuasive as the extension and detection steps of Cheeseman can be interpreted to be “decoupled” given the broad and reasonable interpretation of this term and a size separation step of Schumm et al. was one embodiment not relied on or included in this rejection. Applicant summarizes his invention and reiterates arguments pertaining to Cheeseman and Schumm et al. that were already found unpersuasive as detailed above.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The Central Fax Center number for official correspondence is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (571) 272-0721. The examiner can normally be reached Monday through Thursday from 8 A.M. to 6:30 P.M.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached on (571) 272-0811.

November 16, 2006


Carolyn Smith
Examiner
AU 1631